

CLAIMS

- 5 1. Polymorphic Form E of base ondansetron, characterised in that its powder X-ray diffraction pattern presents characteristic peaks at 6.29°; 11.09°; 11.88°; 12.69°; 14.97° and a doublet at (24.96°; 25.17°) 2 θ .
- 10 2. Polymorphic form according to Claim 1, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2 θ (°)
6.29
7.06
10.50
11.09
11.88
12.69
13.10
13.57
14.97
16.33
16.93
17.40
18.58
19.28
20.71
21.08
21.28
22.10
24.12
24.71
24.96
25.17
25.73
26.65
26.93
28.18
28.53
29.34
29.76

3. Polymorphic form according to Claim 2, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 1.

- 5 4. Process for preparing the polymorphic form according to Claim 1, characterised in that it comprises:
- a) dissolution of the ondansetron hydrochloride in a mixture of a C₁-C₃ alcohol and water;
 - b) precipitation of the base ondansetron by basification
 - 10 of the solution;
 - c) filtering the solid and washing with water;
 - d) suspension of the water-moistened solid obtained in stage c) with methanol at reflux with stirring; and
 - e) recovery of the crystalline form;
 - 15 f) and filtering and drying the product thus obtained.

5. Process according to claim 4, characterised in that said alcohol is methanol.

- 20 6. Process according to Claim 4, characterised in that the basification of stage b) is carried out by addition of an aqueous ammonia solution.

7. Pharmaceutical composition that includes a
25 polymorphic form according to claim 1, in a therapeutically active amount and with a suitable amount of at least one excipient.

8. A polymorphic form according to claim 1 for use
30 for manufacturing a drug for the treatment and prophylaxis of post-operative nausea and vomiting and for the control of nausea and vomiting induced by radiotherapy and cytotoxic chemotherapy.